UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case Number: _____

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS PHARMA AG, NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD. and PROTERRA AG,	:
Plaintiffs,	:
v.	:
APOTEX CORP. and APOTEX INC.,	:
Defendants.	:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG, Novartis International Pharmaceutical Ltd. and Proterra AG (hereinafter "Plaintiffs"), for their Complaint herein against defendants Apotex Corp. and Apotex Inc. allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement.

PARTIES

2. Plaintiff Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

3. Plaintiff Novartis AG ("Novartis AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

4. Plaintiff Novartis Pharma AG ("Pharma AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

5. Plaintiff Novartis International Pharmaceuticals Ltd. ("NIP") is a corporation organized and existing under the laws of Bermuda, having an office and place of business at Hurst Holme, 12 Trott Road, Hamilton HM LX, Bermuda.

6. Plaintiff Proterra AG is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Poststrasse 9, CH-6300 Zug, Switzerland.

7. On information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida.

8. On information and belief, Apotex Inc. is a corporation organized under the laws of Canada, having offices at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

9. On information and belief, Apotex Corp. is a subsidiary of Apotex Inc.

10. On information and belief, the acts of Apotex Corp. complained of herein, were done at the direction of, with the authorization of, and with the cooperation, participation, and assistance of Apotex Inc.

11. Apotex Corp. and Apotex Inc. are referred to hereinafter, collectively as "Apotex."

JURISDICTION AND VENUE

12. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

13. Apotex sells various products and does business throughout the United States, including within this district.

14. Apotex has authorized Ellen Gettenberg of Apotex Corp., 2400 N. Commerce Parkway, Weston, Florida 33326, to accept service of process on behalf of Apotex pursuant to 21 C.F.R. § 314.95(c)(7).

15. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c), and 28 U.S.C. § 1400(b).

CLAIM FOR RELIEF - PATENT INFRINGEMENT

16. Plaintiff NPC holds an approved new drug application ("NDA") No. 20-823 for Exelon® capsules (1.5 mg, 3 mg, 4.5 mg and 6 mg), which capsules contain the active ingredient rivastigmine tartrate (also known as rivastigmine hydrogen tartrate). Exelon® capsules (1.5 mg, 3 mg, 4.5 mg and 6 mg) were approved by the United States Food and Drug Administration ("FDA") on April 21, 2000, for the treatment of mild to moderate dementia of the Alzheimer's type, and subsequently on June 27, 2006, for the treatment of mild to moderate dementia associated with Parkinson's disease, and are sold in the United States by Plaintiff NPC.

17. The active ingredient in the Exelon® capsules, rivastigmine tartrate, is known chemically as (S)-[N-ethyl-3[(1-dimethylamino)ethyl]-N-methyl-phenyl-carbamate] tartrate and as (S)-N-ethyl-N-methyl-3-[1-(dimethylamino)ethyl]-phenyl carbamate hydrogen-(2R, 3R)-tartrate.

18. Proterra AG is the owner of United States Letters Patent No. 4,948,807 ("the '807 patent"). The '807 patent was duly and legally issued on August 14, 1990.

19. The '807 patent claims N-ethyl, N-methyl-3-[1-(dimethylamino)ethyl]phenyl carbamate and pharmaceutically acceptable salts thereof, as well as methods of treating patients that have Alzheimer's disease. A true copy of the '807 patent is attached hereto as Exhibit A.

20. Novartis AG is the owner of United States Letters Patent No. 5,602,176 ("the '176 patent"). The '176 patent was duly and legally issued on February 11, 1997.

21. Novartis AG was formed as a result of the merger of Ciba-Geigy AG and Sandoz Ltd., both of Basel, Switzerland. The '176 patent was initially assigned to Sandoz Ltd. on January 29, 1988, which subsequently became Novartis AG after the merger.

22. The '176 patent claims the (S)-[N-ethyl-3-[(1-dimethylamino)ethyl]-N-methyl-phenyl-carbamate] enantiomer substantially free of its (R) isomer, including the tartrate salt thereof, as well as pharmaceutical compositions and methods of treating conditions such as Alzheimer's disease. A true copy of the '176 patent is attached hereto as Exhibit B.

23. On information and belief, Apotex submitted to the FDA an abbreviated new drug application ("ANDA") under the provisions of 21 U.S.C. § 355(j), seeking

approval to engage in the commercial manufacture, use, and sale of rivastigmine tartrate 1.5 mg, 3 mg, 4.5 mg and 6 mg capsules.

24. On information and belief, Apotex submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of its rivastigmine tartrate 1.5 mg, 3 mg, 4.5 mg and 6 mg capsules before the expiration of the '807 and '176 patents.

25. By filing the ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of its proposed rivastigmine tartrate 1.5 mg, 3 mg, 4.5 mg and 6 mg capsules before the expiration of the '807 and '176 patents, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, the commercial manufacture, use, offer for sale, sale and/or importation of the generic rivastigmine tartrate 1.5 mg, 3 mg, 4.5 mg and 6 mg capsules for which Apotex seeks approval in its ANDA will also infringe one or more claims of the '807 and '176 patents.

26. On information and belief, the Apotex rivastigmine tartrate 1.5 mg, 3 mg, 4.5 mg and 6 mg capsules, if approved, will be administered to human patients in a therapeutically effective amount for treatment of mild to moderate dementia of the Alzheimer's type, which administration constitutes direct infringement of the '807 and '176 patents. On information and belief, this will occur at Apotex's active behest, and with Apotex's intent, knowledge and encouragement. On information and belief, Apotex will actively induce, encourage and abet this administration with knowledge that it is in contravention of the rights under the '807 and '176 patents.

27. On information and belief, Apotex made, and included in its ANDA, a certification under 21 U.S.C. § 355(j)(2)(vii)(IV) that, in its opinion and to the best of its knowledge, the '807 and '176 patents are invalid, unenforceable and/or will not be infringed.

28. On information and belief, Apotex's ANDA seeks approval to manufacture and sell its rivastigmine tartrate 1.5 mg, 3 mg, 4.5 mg and 6 mg capsules, which infringe the '807 and '176 patents.

29. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of the aforementioned ANDA relating to Apotex's rivastigmine tartrate 1.5 mg, 3 mg, 4.5 mg and 6 mg capsules be a date which is not earlier than August 14, 2012, the current expiration date of the '807 patent, and not earlier than February 11, 2014, the expiration date of the '176 patent, and an award of damages for any commercial sale or use of rivastigmine tartrate 1.5 mg, 3 mg, 4.5 mg and 6 mg capsules, and any act committed by Apotex with respect to the subject matter claimed in the '807 and '176 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

30. On information and belief, when Apotex filed its ANDA, it was aware of the '807 and '176 patents and that the filing of its ANDA with the request for its approval prior to the expiration of the '807 and '176 patents was an act of infringement of these patents.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that Apotex has infringed one or more claims of the '807 and '176 patents by filing the aforesaid ANDA relating to Apotex's rivastigmine tartrate 1.5 mg, 3 mg, 4.5 mg and 6 mg capsules;

B. A permanent injunction restraining and enjoining Apotex and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of rivastigmine tartrate 1.5 mg, 3 mg, 4.5 mg and 6 mg capsules as claimed in the '807 and '176 patents;

C. An order that the effective date of any approval of the aforementioned ANDA relating to Apotex's rivastigmine tartrate 1.5 mg, 3 mg, 4.5 mg and 6 mg capsules be a date which is not earlier than the expiration of the right of exclusivity under the '807 and '176 patents;

D. Damages from Apotex for the infringement of the '807 and '176 patents;

E. The costs and reasonable attorney fees of Plaintiffs in this action; and

F. Such other and further relief as the Court may deem just and proper.

Dated: October 27, 2010

/s/Luca Bronzi
Luca R. Bronzi, Esq.
Florida Bar Number: 015628
lbronzi@rmc-attorneys.com
Rivero, Mestre & Castro LLP
2525 Ponce De Leon Blvd.
Suite 1000
Coral Gables, FL 33134
Telephone: (305) 445-2500
Facsimile: (305) 445-2505

Nicholas N. Kallas, Esq.
nkallas@fchs.com
Diego Scambia, Esq.
dscambia@fchs.com
Gregory B. Sephton, Esq.
gsephton@fchs.com
Filko Prugo, Esq.
fprugo@fchs.com

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Telephone: (212) 218-2100
Facsimile: (212) 218-2200

Attorneys for Plaintiffs